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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,289	07/11/2001	Peter A. Burke	3056	8411

7590 09/24/2004
Stephen B. Shear
ARMKEL LLC
469 North Harrison Street
Princeton, NJ 08543-5297

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,289	Applicant(s) BURKE ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The amendment filed June 10, 2004 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-10 and 13-18 have been cancelled
2. Remarks drawn to amendment document containing the omission or non-compliant provision

Claims 11 and 12 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The non-final office action mailed 1/28/2004 contained the rejections of pending claims 11 and 12. Since applicants did not provide a response to the rejections in their amendment of June 10, 2004 the same rejection is contained herein below.

Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larsen (US 5958461) in combination with Ueno et al (US 4869270) and Stoner (US 4925033) of record.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 12 are drawn to a package containing a condom and a spermicidal and a microbicidal composition comprising specific percentages of nonoxynol-9, polyacrylic acid and hyaluronic acid and having a pH of about 5.

Larsen teaches a gelled vaginal composition in the form of a gel, which comprises an acrylic acid modified polymer, an active spermicidal agent and a buffer to maintain the pH of the composition between 3 and 5. The spermicidal agent in Larsen's composition is nonoxynol-9. The composition comprises 1.0 to about 3.0% of the acrylic acid polymer and specifically the pH is between 3.4 to 5.5 (col. 10, lines 13-55; col. 8 examples 2-4). 1% nonoxynol-9 is used in the

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composition (examples 2-4, col. 8). However, Larsen does not teach a composition comprising hyaluronic acid and a lubricating base and a condom in a package.

Ueno et al teach the use of an aqueous solution of the polysaccharide hyaluronic acid with lubricants for applying to the surface of a condom (col. 1, line 55 through col. 2, line 5 and example 4 in col. 3). The composition in example 4 has 1% hyaluronic acid. Ueno et al also disclose that other soluble materials like glycerin, glycols and polyglycols as wetting materials (col. 2, lines 55-60) which one of ordinary skill in the art will realize also can act as lubricants. According to Ueno (col. 1, lines 43-50) the polysaccharide in their composition also serve as lubricants. However, Ueno et al do not teach a composition comprising nonoxynol-9 and polyacrylic acid at a pH of about 5.

Stoner drawn to microbicidal cleansers discloses that spermicide compounds such as nonxynol-9 can also act as anti-microbial agents (col. 1, lines 53-59).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the prior art teachings above to make a package containing a condom and a spermicidal and microbicidal composition as instantly claimed since the active agents and their percentages are seen to be disclosed.

One of ordinary skill in the art would be motivated to do so since combining the composition of Larsen and Ueno to include hyaluronic acid would give a composition that would have a wide spectrum of antimicrobial activity which prevents not only pregnancy and sexually transmitted diseases during sexual encounter but also maintain and enhances the protective function of the vaginal flora (Larsen, col. 3, lines 5-12). Moreover, according to Ueno

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The coating of such a composition on the outside of the condom will have a direct protective effect on the vaginal cavity of the female (Ueno, col. 3, lines 10-19).

Conclusion

1. Claims 11 and 12 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

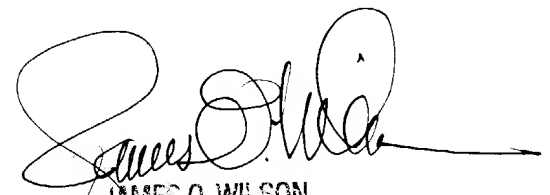
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600